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A randomised clinical trial to evaluate the acceptability and efficacy of an early phase, online, guided augmentation of outpatient care for adults with anorexia nervosa

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Abstract

Background: Outpatient interventions for adult anorexia nervosa typically have a modest impact on weight and eating disorder symptomatology. This study examined whether adding a brief online intervention focused on enhancing motivation to change and the development of a recovery identity (RecoveryMANTRA) would improve outcomes in adults with anorexia nervosa.

Methods: Participants with anorexia nervosa (n=187) were recruited from 22 eating disorder outpatient services throughout the UK. They were randomised to receiving RecoveryMANTRA in addition to treatment as usual (TAU) (n=99; experimental group) or TAU only (n=88; control group). Outcomes were measured at end-of-intervention (six weeks), six months and 12 months.

Results: Adherence rates to RecoveryMANTRA were 83% for the online guidance sessions and 77% for the use of self-help materials (workbook and/or short video-clips). Group differences in body mass index at six weeks (primary outcome), were not significant. Group differences in eating disorder symptoms, psychological wellbeing and work and social adjustment (at six weeks and at follow-up) were not significant, except for a trend-level greater reduction in anxiety at six weeks in the RecoveryMANTRA group ($p=0.06$). However, the RecoveryMANTRA group had significantly higher levels of confidence in own ability to change ($p=0.02$) and alliance with the therapist at the outpatient service ($p=0.005$) compared to the control group at six weeks.

Conclusions: Augmenting outpatient treatment for adult anorexia nervosa with a focus on recovery and motivation produced short-term reductions in anxiety and increased confidence to change and therapeutic alliance.

N=241

Trial Registration number: ISRCTN ClinicalTrials.gov NCT02336841

Key words: Anorexia nervosa; Self-Help; Guidance; Recovery; Trial; Feasibility; Augmentation; Early Symptom Change; Motivation; Online.

A randomised clinical trial to evaluate an early phase online guided augmentation of outpatient care for adults with anorexia nervosa.

Anorexia Nervosa is a psychiatric disorder characterised by prolonged restriction of food intake and severe weight loss (American Psychiatric Association, 2013). This illness is one of the most difficult to treat because starvation impairs a number of areas of functioning, including physical health and psychological wellbeing. Over time, these health consequences create a “snowball effect” that depletes individuals’ resources and chances to recover (Treasure, Stein and Maguire, 2015). Data from naturalistic, long-term follow-up studies suggest that only 40-62% of individuals recover from anorexia nervosa over a period of 20 years (Zipfel *et al.* 2000; Eddy *et al.* 2017; Fichter *et al.* 2017).

One way of optimising treatment efficacy is to augment current interventions in the early phases of treatment. This is based on evidence that rapid symptomatic improvement during the first few weeks of treatment is associated with favourable clinical outcomes at the end of treatment and/or follow-up in adolescents and adult patients (Linardon, Brennan and de la Piedad Garcia, 2016; Wales *et al.* 2016; Nazar *et al.* 2017). To date, there are no published reports on the efficacy of different treatment augmentation strategies in the early phase of adult anorexia nervosa treatment. However, two studies examining the efficacy of short treatment modules to improve patient engagement with standard treatment found that brief interventions focused on psychoeducation and/or motivational enhancement increased the likelihood of treatment engagement compared to a control condition (Brewin *et al.* 2016; Denison-Day *et al.* 2019).

We developed an online, six-week guided self-help intervention, RecoveryMANTRA, to augment treatment as usual for adult outpatients with anorexia nervosa by targeting motivation to change (Cardi *et al.* 2015). The intervention is built upon the cognitive interpersonal model and Maudsley Model of Anorexia Nervosa Treatment for Adults (MANTRA; Schmidt and Treasure, 2006; Treasure and Schmidt, 2013) and conceptualized within a recovery framework. This framework highlights the centrality of peer support, optimism about the future, confidence in one's ability to change, development of identity and meaning, and empowerment (Leamy *et al.* 2011) and uses connections with others and skills-sharing as key aspects of recovery (Smith-Merry, Freeman and Sturdy, 2011). Indeed, a recent systematic review and meta-synthesis on the process of recovery from anorexia nervosa highlighted the importance of addressing a disrupted sense of self and rebuilding identity, a commitment to change, and establishing meaningful relationships with others as a path to self-acceptance (Stockford *et al.* 2018). The emphasis of RecoveryMANTRA is on empowering individuals by increasing their motivation and confidence to change. This is consistent with the assumptions of self-determination theory that underpins the intervention and also with the evidence that a patient's motivation to change predicts clinical outcomes and treatment adherence (Clausen, Lübeck and Jones, 2013; Vall and Wade, 2015; Thaler *et al.* 2016; Denison-Day *et al.* 2018). Furthermore, the goal to strengthen an individual's confidence to change is consistent with the importance of developing a recovery identity that might improve treatment engagement and outcomes (Dingle *et al.* 2015).

The aim of the current study was to examine the acceptability and efficacy of RecoveryMANTRA following assessment for anorexia nervosa at an outpatient service.

It was hypothesised that RecoveryMANTRA, used to augment treatment as usual, would increase BMI at six weeks (primary outcome) and reduce eating disorder symptoms, psychological distress (depression, anxiety, stress) and work and social impairment over time (six weeks and six- and 12-month follow-up). It was also hypothesized that the intervention would increase scores on process measures, such as cognitive and behavioural flexibility, motivation to change and therapeutic alliance. Frequencies of service use (including outpatient treatment, intensive treatment, appointments with general practitioner, family therapy and group therapy) were compared between groups at six and 12 months.

Method

The protocol of this study was published in 2015 (Cardi *et al.* 2015).

Setting and recruitment

Participants were recruited from 22 adult eating disorder outpatient services across the UK (see acknowledgements for details) between April 2015 and December 2016. Informed written consent was sought from participants after complete description of the study. The study received ethical approval from a National Research Ethics Service Committee (London Brent, approval number 14/LO/1347) and from the local research and development offices at the participating centres.

Participants

Patients consecutively assessed at one of the participating centres were recruited if 1) they were aged 16 or over, 2) had a diagnosis of anorexia nervosa according to the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5; American

Psychiatric Association, 2013) or atypical anorexia nervosa (i.e. people who fulfilled all the diagnostic criteria, except the weight criterion; those who fulfilled all criteria but still had menses; those without fat phobia; and those with partial anorexia nervosa, defined as having features of the illness, but missing at least two of the four diagnostic criteria (Thomas, Vartanian and Brownell, 2009), 3) had a body mass index (BMI) of 18.5 kg/m^2 or below and 4) had access to the internet. Participants were considered ineligible if they had 1) insufficient knowledge of English and/or 2) severe mental or physical illness needing treatment (i.e. psychosis or diabetes mellitus). Participant eligibility was assessed using a checklist by the clinicians and clinical study officers recruiting at the centres and clinical diagnoses were confirmed by the clinicians at the participating sites.

The consort diagram in Figure 1 shows the number of participants assessed and randomised to the study groups and also the number of participants who completed the assessment measures at baseline, six weeks, six months and 12 months. Of those assessed for study eligibility ($n = 202$), 187 participants were found to be eligible and were randomised to the RecoveryMANTRA + TAU group ($n = 99$) or to the TAU only group ($n = 88$). The six-week questionnaires were completed by 79.8% and 80.68% of participants in each group, respectively. The six-month questionnaires were completed by 78.79% in the experimental group and 71.59% of participants in the control group. The 12-month BMI data were obtained from 70.05% of the entire sample (see Figure 1).

Randomisation

Participants were randomly allocated to one of two groups: 1) RecoveryMANTRA plus treatment as usual (TAU) or 2) TAU only. TAU in the participating centres was based on the guidelines of the National Institute for Health and

Care Excellence (NICE, 2017), which recommended outpatient care (including psychoeducation, symptom monitoring, psychotherapy) as the first stage of treatment for adults with AN without high medical risk. Randomisation was conducted in Excel by an independent researcher using randomization stratified by participating centre and illness severity (with severe illness defined as BMI <16 kg/m²). Once the database had returned a participant's group allocation, no changes were made.

Intervention

The group allocated to receiving RecoveryMANTRA in addition to TAU had the opportunity to access a workbook, a library of short video-clips (“vodcasts”) and six, one-hour, text-chat sessions with a recovery mentor (either a postgraduate student in psychology, a carer, or an individual recovered from an ED for at least one year). The intervention materials were developed in collaboration with recovered individuals to challenge the ED identity and develop a more positive social, recovery-oriented identity, a feature associated with improved treatment outcomes for other forms of psychopathology, such as depression (Cruwys *et al.* 2014), substance abuse and dependence (Dingle *et al.* 2015; Frings and Albery, 2015), as well as anorexia nervosa (Stockford *et al.* 2018). Motivational interviewing was adopted as the communication strategy throughout the intervention materials to increase confidence and motivation to change. After six months, patients in the control group (i.e. TAU only) were granted access to the intervention materials. For further details on RecoveryMANTRA and its theoretical background, please refer to the study protocol paper (Cardi *et al.* 2015).

Treatment fidelity

Recovery mentors (postgraduate psychology students, $n = 13$; carers, $n = 2$; or people recovered from an ED who had been weight-recovered and ED symptom-free for at least 24 months, $n = 9$) completed two mandatory three-day trainings in motivational interviewing and implementation of RecoveryMANTRA. Two-day “booster” training sessions were also offered twice a year. Recovery mentors also received weekly email or telephone supervision based on session transcripts by one of two clinical supervisors with extensive experience in the treatment of EDs.

Assessments

Eligible participants accessed assessments and RecoveryMANTRA materials online through IESO Digital Health (<http://www.iesohealth.com>). Participants completed self-report questionnaires on the online platform at baseline, six weeks, six months and 12 months. Assessments were prompted by a research assistant sending an email reminder through the online platform the day before the assessments were due. After completion of the baseline assessment, participants were randomised to one of the two study groups and their clinicians at the participating site were kept blind to this allocation. Although all study measures were collected online and completed as self-reports, the clinical teams (blind to treatment allocation) were contacted to report on BMI at six weeks, six months and 12 months to recover missing data. The research team did not measure participants’ weight and height at assessment or follow-up because patients were recruited from all over the UK and face-to-face research assessments were not feasible.

Self-reported clinical measures. Eating disorder symptoms were assessed using the Eating Disorder Examination Questionnaire (Fairburn and Beglin, 1994); mood was

measured using the Depression, Anxiety and Stress Scales (Lovibond and Lovibond, 1995) and quality of life was assessed using the Work and Social Adjustment Scale (Mundt *et al.* 2002). These measures were assessed at baseline, six weeks, six months and 12 months.

Self-reported process measures. Motivation for treatment was assessed at baseline and six weeks using The Autonomous and Controlled Motivations for Treatment Questionnaire (Zuroff *et al.* 2007; adapted from Williams *et al.* 1998). This measure assesses people's intrinsic, internally generated motivation to change (i.e. autonomous motivation), as well as motivation to change due to external demands and pressures (i.e. controlled motivation). Motivation to change was assessed at baseline, six weeks, six months and 12 months, using two visual analogue scales (scales ranging from 0 to 10 and measuring confidence in one's own ability to change and importance to change). Alliance with the therapist at the outpatient service was measured at baseline and six weeks, using five, 7-point visual analogue scales developed by the study team (i.e. the scales measured levels of: therapist's understanding, confidence in therapist's ability to point towards the right direction of change, mutual agreement on therapeutic goals, trust, and ability of therapist to offer new ways of looking at the problem; an average total score was used for the analyses). Cognitive and behavioural flexibility was measured at baseline and six weeks, using two, seven-point visual analogue scales developed by the study team (i.e. the scales measured the extent to which participants pay attention to small details at the detriment of seeing the bigger picture and the extent to which they need to adhere to rules and rituals in their behaviour; average total score was used for the analyses).

Participants service use. This was assessed asking participants to report on the usage of clinical services (including outpatient treatment, inpatient or daycare services, group therapy, family therapy, and appointments with the general practitioner) over the previous six and 12 months.

Assessment of RecoveryMANTRA intervention usage. The number of one-hour, chat-based sessions attended was recorded for each participant in the RecoveryMANTRA arm. Based on average completion rates reported in systematic reviews of individual psychotherapy (20-40%; Dejong, Broadbent and Schmidt, 2012) and technology-based interventions (57.6%; Schlegl *et al.* 2015) for eating disorders, we set an *a priori* definition of “completion” as attendance at a minimum of four of the six offered sessions. Participants also completed daily ratings of usage of workbook and video clips over the six weeks (42 days).

Statistical Analyses

All analyses were conducted in SPSS version 24.0 (SPSS, Inc., USA). Univariate analyses of variance were used to compare the intervention (RecoveryMANTRA + TAU) and control (TAU alone) groups on the sociodemographic, clinical and process continuous variables separately at six weeks, six months and 12 months. Logistic regression was used for dichotomous measures. Covariates for all models included baseline observations. All analyses were based on an intention-to-treat (ITT) approach, except for the frequency of using clinical services. Missing data for outcomes at six weeks, six months and 12 months were imputed using multiple imputation based upon the Markov chain Monte Carlo method (Schafer, 1997) and maximum likelihood

imputation based upon the Expectation-Maximization (EM) algorithm. Results were compared across the two methods. Effect sizes for the outcomes were established using Cohen's d and interpreted as small (0.2), medium (0.5) and large (0.8) (Cohen, 1988).

The primary outcome was body mass index at six weeks. Secondary outcomes were body mass index at six months and 12 months, eating disorder symptoms (EDE-Q total score), depression, anxiety and stress scores (DASS-21) and work and social adjustment (WSAS) at six weeks, six months and 12 months. Process measures were autonomous and controlled motivation for treatment, confidence in own ability to change and importance to change, and cognitive and behavioural flexibility. Frequencies of clinical services' use were compared between groups using Pearson's Chi-squared tests.

Results

Participants' characteristics

One-hundred eighty-seven participants (including $n=181$ females) completed the baseline assessment (see Table 1 for demographic and descriptive information). This is within the target sample size ($n=180$) resulting from the power calculation reported in our protocol paper (Cardi et al., 2015). There were not significant differences in demographic or clinical variables between the control and intervention groups at baseline, except for a trend-level difference in BMI ($p = .06$; higher BMI in the TAU only group). Participants had suffered from an eating disorder for 7.76 years on average ($SD= 8.91$), and 22% ($n=42$) had had previous hospital admissions. At the time of recruitment, 123 participants (70.3%) had started outpatient treatment following assessment. As noted in Table 1, assessment of functioning indicated clinically significant elevations on eating

disorder symptoms (EDE-Q) and moderate to severe levels of depression, anxiety, and stress (DASS-21). Mean scores on the Work and Social Adjustment Scale (WSAS) indicated significant functional impairments.

Completion of guidance sessions and use of self-help materials

Eighty-two individuals completed four or more of the six guidance sessions (82.83%; Figure 1). The self-help materials (workbook and/or video-clips) were accessed by 76.77% of the participants (76/99) in total. Frequency of usage for the self-help materials was variable, with some accessing the resources once ($n = 6$), between 6-10 times ($n = 21$), and up to 21-26 times ($n = 9$) over the course of the six week intervention period.

Primary and secondary outcomes

Differences between groups are described in Table 2. No significant group differences in BMI were found at six weeks (primary outcome). No significant differences between groups were found on BMI at six and 12 months and no significant differences were found on eating disorder symptoms, depression, stress and work and social adjustment at any time points. There was a trend-level difference in anxiety scores between groups at six weeks ($p = 0.06$), with a reduction in anxiety in the intervention group and an increase in the control group.

Analyses were repeated after data were imputed with maximum likelihood imputation based upon the Expectation-Maximization (EM) algorithm. The same patterns of findings were found, overall (Table S1).

Process measures

Differences between groups were explored with regard to process measures (i.e. cognitive and behavioural flexibility, autonomous and controlled motivation for treatment, importance and confidence in own ability to change and alliance with therapist at the outpatient service) (Table 2). Significant differences between groups were found on confidence in own ability to change and alliance with therapist at six weeks ($p= 0.02$ and $p= 0.005$, respectively), both of which were higher in the intervention group. Group differences in confidence in own ability to change reduced over time and were no longer significant at six or 12 months. Group differences on the other process measures were not statistically significant. The type of mentor allocated to participants (either a postgraduate student in psychology, or a carer, or an individual recovered from an ED) did not affect the pattern of findings.

Similar findings were obtained when data were imputed using maximum likelihood imputation based upon the Expectation-Maximization (EM) algorithm (Table S1), with the exception of importance to change, which also increased significantly more in the intervention group, compared to the control group, at six weeks ($p= 0.03$).

Service use

At six months, a greater proportion of participants in the RecoveryMANTRA group (88.31%) than the control group (71.42%) were still attending outpatient treatment, $X^2(1) = 6.34$; $p = .01$. This difference was not significant at 12 months, $X^2(1) = .85$; $p = 0.35$. There were no other significant differences between groups in terms of frequency of service use over the previous six or 12 months, including use of intensive treatment (inpatient or day-care), visits to general practitioner, group therapy and family therapy.

Discussion

The aim of this study was to test the acceptability and efficacy of adding an online self-help intervention, RecoveryMANTRA, to augment outpatient treatment for anorexia nervosa. There was a reasonably high level of adherence (with 83% completing four or more sessions) to the online guidance which adopted a motivational interviewing framework. Additionally, over three quarters of our participants accessed the self-help videos and workbook at some point during the six-week intervention. However, the usage of the self-help videos and workbook materials was variable across respondents, with some demonstrating high levels of use and others accessing the resources infrequently. The intervention did not produce between-group differences in body mass index, but there was a greater trend-level reduction of anxiety symptoms in the RecoveryMANTRA group at six weeks, compared to an increase in anxiety in the control group. This effect was no longer significant at six- and 12-month follow-up. Group differences on eating disorder symptoms or other indicators of well-being such as depression, stress and work and social adjustment were negligible. These findings align with those described in a recent meta-analysis of specialised treatments in anorexia nervosa, which found lack of superiority effects over standard treatment on improving weight and psychological outcomes at follow-up (Murray *et al.* 2019). Similarly to other treatment trials (e.g., Zipfel *et al.*, 2014; Schmidt *et al.*, 2016; Byrne *et al.*, 2017), participants in this study had clinical features associated with a worse prognosis, including long duration of illness and low weight. Furthermore, they were receiving outpatient treatment at their clinical sites and RecoveryMANTRA was compared against this. Both severity of symptoms and

concurrent outpatient treatment might limit the impact of RecoveryMANTRA and explain the lack of augmentation effects on BMI and core eating disorder symptoms.

The target outcomes of the motivational interviewing strategies employed by recovery mentors (i.e. confidence in own ability to change and alliance with TAU therapists) increased at six weeks in the intervention group. This indicates good fidelity and adherence to the model. These results are consistent with recent findings from a multisite outpatient trial of Cognitive-Behavioural Therapy for anorexia nervosa, which reported that the motivational enhancement module was the most commonly used, thereby attesting to the value of motivational strategies to tackle the core feature of ambivalence in anorexia nervosa (Resmark *et al.* 2018).

Strengths and limitations

The current study has several strengths, some of which have been considered critical for improving the quality and clinical usefulness of RCTs in eating disorders (Lock *et al.* 2018; Wade, Johnson and Byrne, 2018). A protocol paper was published when the trial started (Cardi *et al.* 2015b) with a full description of rationale, methods and plans for analyses, ensuring that no changes to the original plan were made based on the trials' findings. Missing data were addressed by intention-to-treat analyses and by using two different ways of imputing missing data; randomisation biases were minimised using block randomisation and adjustment for baseline variables in the analyses. External validity of the study was ensured by the involvement of many different services across the UK (thereby reflecting real life clinical practice with no control over TAU) and the inclusion of typical, as well as atypical presentations of anorexia nervosa. A range of outcomes were used to capture changes in transdiagnostic psychological variables above

and beyond eating disorder-related outcomes (i.e. weight and eating disorder symptoms; Murray, Loeb, Le Grange, 2018). The sample size was above minimal requirements for capturing clinically significant treatment effects ($n = 50$; Kraemer and Thienemann, 1987) and attrition rates were within the lower end of those typically observed in the field (20%-40%; DeJong *et al.* 2012).

A possible limitation of this study is that participants' access to the internet was not assessed continuously throughout the project. Difficulties accessing the internet might explain the modest use of online self-help materials. However, patients' ambivalence towards change might also account for the sub-optimal use of self-help materials which did not involve direct supervision from the mentor. A further limitation is that patients' weight and height (main study outcome) were not directly measured by the study team. This is because participants were recruited from all over the UK and face-to-face research assessments were not feasible.

Clinical implications

It is somewhat surprising that improvements in therapist alliance and confidence in own ability to change were not matched by improvements in weight and eating disorder psychopathology as there is evidence that these common factors in psychotherapy are major drivers of clinical symptom change in the treatment of anorexia nervosa (Sly *et al.* 2013; Brauhardt, de Zwaan and Hilbert, 2014). The lack of effect may be, in part, because of the suboptimal match between the primary and secondary outcomes (i.e. BMI and eating disorder symptoms) with the contents of the self-help materials and guidance (intra- and inter-personal maintaining factors, recovery identity, motivational enhancement). Upon reflection, the psychological processes targeted (and

successfully changed) in the intervention might need more intense and sustained efforts (i.e. longer duration, more guidance) to translate into changes in weight and core eating disorder symptoms in this participant group who, for the most part, have shown themselves to be resistant to treatment. Alternatively, recent findings suggest that exposure to recovery narratives may not directly increase motivation to change, or could evoke positive as well as negative (e.g. social comparative) responses, thus highlighting the need for further assessment of underlying mechanisms for recovery narratives and alternative strategies for presentation of these stories (Dawson *et al.* 2018). It is also possible that the format of our intervention failed to optimise reflection and adoption of a recovery identity through increasing social support. For example, clinical observations from a trial in progress testing online guided self-help for patients with anorexia nervosa and their carers to facilitate transition from intensive hospital treatment into the community (Cardi *et al.* 2017) indicate that strengthening social connection by improving patient-to-patient support and support from carers is highly valued by participants.

Conclusions

RecoveryMANTRA increased confidence in the person's own ability to change and therapeutic alliance with TAU clinicians in the short-term. The intervention was also associated with small-sized improvements in anxiety compared to the control group. More extended periods of guidance and/or a greater focus on interpersonal elements might improve clinical outcomes over time. Strategies such as inviting carers to provide support and encourage use of self-help materials (Hibbs *et al.* 2015; Cardi *et al.* 2017) and greater utilization of peer support to strengthen the recovery identity (Leamy *et al.* 2011) might better augment outpatient interventions for anorexia nervosa.

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